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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/441,654	11/12/1999	SHAM-YUEN CHAN	MSB-7263	4743

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EXAMINER

BUGAISKY, GABRIELE E

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 06/19/2003

24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/441,654

Applicant(s)

CHAN, SHAM-YUEN

Examiner

Gabriele E. BUGAISKY

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,6-9,15,18-21,25 and 26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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The amendment of 2/26/2003 is acknowledged. Claims 2 and 15 have been amended, .
Claims currently pending and under consideration are 2, 6-9, 15, 19-21 and 25-26.

Specification

The disclosure remains objected to because of the following informalities: patent application numbers remain in the disclosure.

Appropriate correction is required.

The amendment filed 2/26/2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: reference is now made to an application filed **AFTER** the filing date of this application.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

While the Examiner maintains that the glycosylation pattern of human hepatocyte growth factor activator inhibitor type 2 from conditioned medium of MKN45 cells is an inherent feature,

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the rejection of claims 2 and 6-9 and 25 under 35 U.S.C. 102(b) as being anticipated by Kawaguchi *et al.* is withdrawn, in favor of the following rejection:

Claims 2, 6-9 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Shimomura *et al.* (US patent 5731412) Shimomura *et al.* provides for purification of human hepatocyte growth factor activator inhibitor type 2 from conditioned medium of MKN45 cells; the primary amino acid sequence of human hepatocyte growth factor activator inhibitor type 2 is identical to instant SEQ ID NO:1 and thus has the identity of placental bikunin. The reference is deemed anticipatory for the claimed subject matter because the cloned human hepatocyte growth factor activator is expressed in and isolated from COS cells. (see Example 8) The glycosylation pattern is presumed to be identical in COS cells, which are the same cells used to produce the glycosylated bikunin of the instant application. With respect to the recited pharmaceutically acceptable carrier, the protein activity was assayed in PBS.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The rejection of claims 15,18-21 and 26 under 35 U.S.C. 103(a) as being unpatentable over Gentz *et al.* in view of Gribben *et al.* and Hotchkiss *et al.* is withdrawn, based upon the amendment.

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Claims 15,18-21 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimomura et al. in view of Delaria *et al.* Shimomura *et al.* is discussed above. They do not test the activity of each Kunitz domain against human hepatocyte growth factor activator. Delaria *et al.* provide monokunins produced in Sf-1 cells and tests their activity against the factor VIIa-tissue factor complex and factor Xa, but does not test it against human hepatocyte growth factor activator. It would have been obvious for one of skill in the art at the time of the invention to produce the single Kunitz domains of Delaria *et al.* in the CHO culture system of Shimomura et al., with the intended use for testing each glycosylated domain for activity against human hepatocyte growth factor activator. One would have had a very high expectation of success in the venture.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

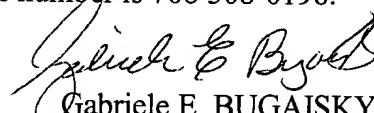
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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gabriele E. BUGAISKY whose telephone number is (703)308-4201. The examiner can normally be reached on 8:15 AM- 2 PM, Tu & Th, 8:15 AM-1:30 PM, We & Fr.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher SF Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are 703 308-4242 for regular communications and 703 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 708 308-0196.


Gabriele E. BUGAISKY
Primary Examiner
Art Unit 1653

June 16, 2003